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#### REMARKS

Claims 1 to 23, 25 and 26 are pending in this application and are the subject of the following rejections. Claim 24 has been deleted for reasons unrelated to patentability. Claims 10 and 20 have been amended without prejudice for reasons unrelated to patentability and no new matter has been added. Applicant traverses each rejection as follows.

Applicant respectfully acknowledges the cancellation of claims 27-74 and the addition of claims 25 and 26 to elected Group I.

## 35 U.S.C. §112, second paragraph

The Examiner rejected claims 1 to 24 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter. Applicant traverses this rejection for at least the following reasons.

The Examiner asserts that "'effective amount' is not stated as to what effective for."

However, Applicant directs the Examiner's attention to page 7 of the specification, where effective amount is defined as "an amount of imidacloprid, spinosad, spinosyn, Spinosyn A, Spinosyn D or a combination thereof sufficient to decrease the number of live lice and viable nits, i.e. eggs." The range of the amounts are also described on page 7 of the specification.

The Examiner has rejected claims 8 and 34 because "greater than - about" is allegedly indefinite. Applicant traverses this rejection and directs the Examiner's attention to MPEP § 2173.05(b) and (c). "Exceeding about" was held to be definite as stated in MPEP § 2173.05(b)(A), and "greater than about" is synonymous with "exceeding about," therefore it is also definite.

The Examiner has required that Applicant spell out abbreviation at first appearance in claims. Applicant has amended claims 10 and 20 for reasons not related to patentability, and respectfully asserts that this rejection has been overcome.

The Examiner asserted that "long chain" is indefinite, and it is unclear what 'stabilizers' is intended to encompass. Applicant directs attention to page 16 of the specification, where examples of long chain acyl derivatives and esters of long chain fatty acids are described.

Further, page 15 and 16 of the specification define "stabilizers" and list examples of "stabilizers." Therefore, Applicant asserts this rejection has been overcome.

Additionally, the Examiner asserts that "R" is unspecified in claim 1. Applicant directs the Examiner's attention to "R" in the chemical structure of claim 1 at the bottom center.

Applicant is unclear what Examiner means by "there is no antecedent basis for S. spinoso components in claim 1." S. spinoso components is not a term in claim 1. Applicant requests clarification of this rejection.

Finally, claims 18, 25 and 26 have been amended to replace the tradename ceteareth-20 with a generic form. Applicant asserts that the rejection under 35 U.S.C. 112, second paragraph has been overcome.

#### 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1 to 24 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, with which it is most nearly connected, to make and/or use the invention. According to the Examiner, one of ordinary skill in the art would need to perform excessive experimentation to determine efficacious, if any, amounts and combinations of all structures and compounds encompassed by generic claim structure, and/or that of the S.

spinosa components. Applicant respectfully submits that the specification is replete with teachings enabling a person skilled in the art to practice this invention.

Applicant respectfully submits that so long as the experimentation required for practicing the invention is routine, the extent of such experimentation is immaterial to § 112 requirements. The Federal Circuit supported Applicant's view in *In re Wands*, 8 U.S.P.Q.2d 1400, 858 F.2d 731 (Fed. Cir. 1988), which stated the test whether experimentation required to practice an invention is undue,

is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

In re Wands, 8 U.S.P.Q.2d 1400, 858 F.2d 731 (Fed. Cir. 1988)

In order to practice the *Wands* invention, extensive (but not undue) experimentation was required, but this did not preclude a finding that the *Wands* claims were enabled. Therefore, since Applicant's claims do not require undue experimentation, Applicant's claims are still enabled. The specification teaches what the invention is and how to use it, so that one skilled in the art can practice the invention as claimed without the burden of undue experimentation, and § 112 is satisfied. If the Examiner believes that it would be qualitatively un-routine to duplicate the Applicant's invention based upon the specification, Applicant invites the Examiner to cite evidence or offer a declaration to this effect.

The Examiner has requested information regarding PVM/MA. Applicant notes that one of the pieces of art cited by the Examiner uses the term PVM/MA (Castro Col. 1, line 52). Since the term is used in the art, one of ordinary skill in the art would know its meaning. However, Applicant also supplements the information with PVM/MA product information (Attached as Exhibit A). PVM/MA is an abbreviation used in the art, as is found in a list of Chemical

Abbreviations found on

www.silverplatter.com/newFieldGuides/euci/Chemical abbreviations.
htm(a copy of which is attached as Exhibit B).

# 35 U.S.C. § 102

Applicant notes that the filing date of this application was April 25, 2001, which is after November 29, 2000, and therefore the AIPA changes do apply to § 102(e).

Claims 1 to 10, and 12 to 24 are rejected under 35 U.S.C. § 102(e) as being anticipated by Snyder (US Patent No. 6,063,771). Applicant traverses this rejection for at least the following reasons.

Independent claims 1 and 24 (from which all of the relevant claims depend) are each limited to "an effective amount of one or more agents having pediculicidal and ovacidal properties for adult lice and nits of a specie of order Anoplura in solution." (emphasis added). Snyder teaches dispersions, and does not teach solutions, and therefore cannot anticipate these claims.

In column 18, line 60 to column 19, line 4, Snyder adds spinosad to a shampoo.

The wet milling process described is used when preparing a dispersion, facilitating particle size reduction. If the composition was soluble, a wet milling process would not be used.

Conventional mixing equipment would be sufficient to mix a solution.

Further, Snyder teaches the use of suspending agents in column 8, line 40, and claim 6.

Nothing in Snyder shows that the amount and types of solvents used for solution were known.

Since Snyder employs suspending agents "to improve long term stability," (col.8, line 40), this does not teach a solution, because a solution does not require a suspending agent for stability.

Finally, some of the dependent claims (11 and 20) and independent claims 25 and 26 in the pending application require BHT, PVM/MA and/or specified percentages of each ingredient. The Examiner has admitted that Snyder "does not specify" these elements, and therefore cannot anticipate these claims.

Therefore, Snyder does not teach each element of the claims, and cannot anticipate the pending claims under 35 U.S.C. § 102.

## 35 U.S.C. § 103

Claims 1 to 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Snyder in view of Castro and Vermeer. Applicant traverses the rejection for at least the following reasons. The Examiner cites Castro to show "that topical application formulations include the instantly claimed PVM-Ma deadiene copolymer... equivalent to Snyder's guar gum, and expressly identifying Snyder's generally described ethylene/MA carbopol copolymers." "Vermeer is cited to show BHT is a common preservative (antioxidant)used in aqueous hair care/skin care/shampoo compositions."

As noted in the § 102 discussion, Snyder does not teach a solution, which is an element of each of the claims. Neither Castro¹ nor Vermeer, even assuming arguendo that the Examiner's assertions are correct, teach a solution which would be obvious in light of Snyder. Therefore, the rejection has been overcome and Applicant requests that it be withdrawn.

#### CONCLUSION

Castro is in the cosmetic art for self-tanning mousse. One of ordinary skill in the art would not look to self-tanning cosmetic art to further develop a pediculicidal or ovacidal composition.

Applicant respectfully asserts that the application is in condition for allowance.

Reconsideration and the early issuance of a Notice of Allowance are requested. If the Examiner has any outstanding issues, the courtesy of a phonecall is requested.

# Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees or credit any overpayment, to Deposit Account 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith for application Serial No. 09/841,715 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703 872 9306 on the data, shown below.

Maryellen Feshery

October 28, 2002

Date of Facsimile Transmission

Respectfully submitted,

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## AMENDMENTS (changes noted)

- 10. (amended) The composition claim 2, wherein the stabilizers comprise one or more of the group consisting of polyvinyl methyl ether/maleic anhydride [PVM/MA] Decadiene crosspolymers, acrylates/aminoacrylates C10-30 Alkyl PEG-20 Itaconate copolymer, long chain acyl derivatives, alkanolamides, esters of long chain of fatty acids, alkyl dimethylamine oxides, methylcellulose, hydroxybutyl methylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, hydroxybutyl methylcellulose, distearyl phthalic amide, di(hydrogenated) tallow phthalic amide, primary amines with a fatty alkyl moiety of at least 16 carbons, polyacrylic acids, polysaccharide gums, colloidal clays and colloidal silica.
- 18. (amended) The composition of claim 15 wherein the emulsifying agent comprises polyethylene glycol ether of cetearyl alcohol [Ceteareth-20].
- 20. (amended) The composition of claim 15 wherein the antioxidant comprises <u>butylated</u> <u>hydroxytoluene[BHT]</u>.
- 24. (deleted)
- 25. (amended) A composition comprising:

About 44% water;

About 1.1% PVM/MA Decadiene crosspolymers;

About 3% propylene glycol;

About 3% cetearyl alcohol;

About 0.9% polyethylene glycol ether of cetearyl alcohol [ceteareth-20];

About 4.17% stearalkonium chloride;

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About 10% benzyl alcohol;
       About 6% hexylene glycol;
       About 4% pentylene glycol;
       About 20% isopropyl alcohol;
       About 2.19% mixture of spinosyn A & D in an approximate 85:15 weight ratio;
       About 0.1% BHT; and
      About 1.29% sodium hydroxide (10% solution).
26. (amended) A composition comprising:
       Water;
      A PVM/MA Decadiene crosspolymers;
      Propylene glycol;
      A mixture of cetyl and stearyl alcohols;
      polyethylene glycol ether of cetearyl alcohol [Ceteareth-20];
      Stearalkonium chloride;
      Benzyl alcohol;
      Pentylene glycol;'
      Isopropyl alcohol;
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A mixture of spinosyn A and spinosyn D in a weight ratio of approximately 85:15;

BHT; and

Sodium hydroxide.